

REMARKS

By the foregoing Amendment, Claims 1, 5, 11, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 30-32, 36, 37 and 38 have been amended. It is believed that no new matter has been added, and the amendment of the claims is intended to be fully responsive to the Office Action of March 30, 2004. Favorable reconsideration of the application is respectfully requested.

Claims 1-38 were rejected under 35 U.S.C. 112, second paragraph, on the grounds of indefiniteness. The claims have been amended in accordance with the Examiner's suggestions and to clarify the wording of the claims for consistency, with the exception of Claim 38. Claim 38 was rejected on the grounds of indefiniteness for omitting "a step of adjusting the pH of the suspension to about 6.7 to 6.8 followed by a step of incubating." The Examiner indicated that these steps were included in Fig. 1, the description at pages 2 and 4, and in original Claim 1. It is initially noted that Fig. recites the pH range as being "pH 5.70-5.80," and Claim 1 was amended in the preliminary amendment of May 30, 2003, received June 6, 2003, to recite "adjusting the pH of the suspension to about 5.7 to 5.8." The specification at page 2, line 9, recited the pH as "between 5.7 and 5.8," and the specification was amended in the preliminary amendment of May 30, 2003, received June 6, 2003, to recite at page 4, line 5 "pH 5.7 to 5.8." Claim 38 has been amended to recite "adjusting the pH of the suspension to about 5.7 to 5.8," as is recited in Claim 1, and as is consistent with the disclosure.

The Examiner indicated the step of incubating was considered essential, but the Examiner's attention is directed to the specification at page 4, lines 16-20, where it is disclosed that the step of incubating is not essential, in that "Alternatively, liquid-separation of the suspension can be performed at this step in the process, rather than incubation of the suspension, followed by repetition of the earlier steps of preparing the suspension and precipitating the same." It is therefore respectfully submitted that the step of incubating the suspension is not essential to the invention. It is respectfully submitted that the rejection of Claims 1-38 on the grounds of indefiniteness now can be withdrawn.

Claims 20-21 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, which the Examiner indicated could be overcome by deleting "solution" in line 2. The term "solution" has been deleted in Claim 20 at line 2, and in Claim 21 at line 2, so that it is believed that the rejection of Claims 20-21 as failing to comply with the written description requirement can be withdrawn.

Claim 38 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, on the grounds that Claim 38 recites new matter by virtue of not reciting the temperature range of -4°C to -6°C in the step of suspending, and failing to recite adjusting the pH of the suspension to about 6.7 to 6.8. Claim 38 has now been amended to recite "suspending the immune globulins in an ethanol solution at a volume equivalent to two times that of the plasma source at a temperature in a range of about -4°C to -6°C; adjusting the pH of the suspension to about 5.7 to 5.8." The Examiner indicated that the disclosure at page 4, line 5 recited "pH 6.7 to 6.8" rendering

the disclosure inconsistent with respect to the disclosure in Fig. 1 and at page 2, line 9.

As was noted above, the specification was amended in the preliminary amendment of May 30, 2003, received June 6, 2003, to recite at page 4, line 5 "pH 5.7 to 5.8."

The Examiner further indicated that Claim 38 introduces new matter by failing to recite the incubating step, and that Applicant improperly broadened the scope of the invention. The Examiner further rejected Claim 38 under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling in that the step of adjusting the pH of the suspension to about 6.7 to about 6.8 followed by a step of incubating are critical or essential to the practice of the invention, but not included in Claim 38. As noted above, Claim 38 has now been amended to recite " adjusting the pH of the suspension to about 5.7 to 5.8." Also as noted above, it is respectfully submitted that the step of incubating is not essential, in that it is disclosed in the specification at page 4, lines 16-20, that "Alternatively, liquid-separation of the suspension can be performed at this step in the process, rather than incubation of the suspension, followed by repetition of the earlier steps of preparing the suspension and precipitating the same." It is therefore respectfully submitted that the rejection of Claim 38 on the grounds of lack of enablement by the disclosure should be withdrawn.

Applicant wishes to thank the Examiner for the indication that Claims 1-38 are considered to be allowable over the prior art.

In light of the foregoing amendments and the foregoing remarks, it is respectfully submitted that the application is now in condition for allowance, and an early favorable action in this regard is respectfully requested.

The Examiner is encouraged to telephone the undersigned if there are any remaining issues as to the wording of the claims or any other issues remaining as to the allowability of the claims.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: 

James W. Paul
Reg. No. 29,967

JWP/rvw

Encls.: Return Postcard

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201
53022.1